



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/147,770	04/28/99	DEL SOLDATO	P P8907-9002

HM12/0214
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EXAMINER

TRAVERS, R

ART UNIT

PAPER NUMBER

1617 //

DATE MAILED: 02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/147,770

Applicant(s)

Del Soldato et al

Examiner

RUSSELL TRAVERS

Group Art Unit

1617



☒ Responsive to communication(s) filed on Nov 22, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-10 is/are pending in the application.

Of the above, claim(s) 6-8 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-5, 9, and 10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit:

The response and amendment filed November 22, 2000 has been received and entered into the file.

Claims 1-10 are presented for examination.

Applicant's election without traverse of Group I, claims 1-5 in Paper No. 10 is acknowledged.

Claims 6-8, reading on non-elected subject matter are withdrawn from consideration. Claims 1-5 and 9-10 will be examined to the extent they read on the elected subject matter.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals &

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Interferences in *Ex parte Wu*, 10 USPQ2d 2300 (BdApls 1989) at 2303, as to where broad language is followed by "such as" and then narrow language. The Board stated, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. In the present instance, claims 1-5 recite the broad recitation of various compounds for the intended use, and the claim also recites, "preferred are the compounds where", which is a narrower statement of the range/limitation. Applicants recitation of the broad range or limitation together with a narrow range or limitation renders independent claim 1 and dependant claims 2-5 properly rejected as indefinite.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed

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invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-5 and 9-10 are rejected under 35 U.S.C. § 103 as being unpatentable over Merck Index #4852 and Morikawa et al.

Merck Index #4852 teach indomethacin as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as useful for treating inflammation. Morikawa et al teach indomethacin as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as useful for increasing the time to micturition, and increasing bladder pressure threshold. Compounds taught as useful for increasing the time to micturition, and increasing bladder pressure would have been seen as useful for treating urinary incontinence by the skilled artisan. Claims 1-5 and 9-10, and the primary references, differ as to:

- 1) the recitation of those medicaments set forth in claims 9 and 10.

The skilled artisan, possessing a compound for a therapeutic use possesses that compounds analogs, homologs, isomers, bioisosteres, salts, acids and esters for the same use. To employ an analog, homolog, isomer, bioisostere, salts acid and ester for the same use therapeutic use would have been obvious to the skilled artisan. Prior art use for the same therapeutic purpose would have motivated the skilled artisan

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to employ indomethacin esters to the same therapeutic use and enjoy a reasonable expectation of therapeutic success.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

A handwritten signature in black ink, appearing to be 'RS' with a large loop and a trailing line.

**Russell Travers
Primary Examiner
Art Unit 1617**